IRB Approval Date (OHR Staff Only)

Informed Consent for Research Participation

Title of research study: Standardization of Functional Status Items

IRB#

Investigator: Trudy Mallinson, PhD, OTR/L

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you receive services from a Home and Community Based Services waiver program, which is part of Medicaid long-term services and supports.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the study investigator, Trudy Mallinson at 202-994-6833 or via email at trudy@gwu.edu.

This research is being overseen by an Institutional Review Board ("IRB"). You may talk to them at 202-994-2715 or via email at ohrirb@gwu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You have questions about your rights as a research subject.

Why is this research being done?

This research is being done in order to create a national standardized assessment of functional status for individuals using community based long-term services and supports. Functional status refers to how you do your everyday activities such as walking and taking care of yourself at home. The questions on the assessment form are being tested to see how well they work. In the future, these questions may be used to help states determine eligibility for home and community-based programs, service planning, resource allocation, and evaluating the quality of care provided by the programs. Currently there is no standard way to ask these questions but this study is working to create that standard.

How long will the research last?

We expect that the assessment will take between 30 minutes and an hour. There will only be one appointment. After that appointment, your participation in the study will be over.

How many people will be studied?

We expect about 1,570 people will take part in the entire study.

What happens if I agree to be in this research?

If you agree to be in this research, the assessor will ask you questions about your need for assistance to do everyday activities like getting dressed, preparing a meal, or going shopping. The assessor may also ask to watch you complete simple activities like moving around your home or getting up from a chair. The assessor will record your answers and describe your performance on the score sheet. This information will be used by the research team to help make the questions better in the future. This information will not be used for your program eligibility or services. The assessment should take between 30 minutes to an hour. There will only be one assessment. There will not be any follow-up visits.

The assessment will be done by a professional who has been trained to complete this form and who works with your state doing these sorts of assessments. The assessment will begin once you provide consent. Once all the data are collected, the results will be sent to the George Washington University to perform analyses and determine how to make the questions better.

What other choices do I have besides taking part in the research?

This study only involves completing the assessment tool. You do not have to participate in this study.

What happens if I agree to be in research, but later change my mind?

You can decide to not be in the study at any time. If you decide to leave the research, nothing will happen to you and your services will not change. If you stop being in the research, already collected data may not be removed from the study database.

Is there any way being in this study could be bad for me?

There is a chance of a loss of confidentiality and discomfort due to asking personal questions during the interview.

The risks and discomforts associated with participation in this study are not greater than those ordinarily encountered in daily life or during the performance or routine physical or psychological examinations or tests.

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. However, the benefit to society may be to help create a more useful assessment for that can be used to evaluate need for services for beneficiaries of the Home and Community Based Services programs.

What happens to the information collected for the research?

To the extent allowed by law, we limit your personal information to people who have to review it. We cannot promise complete secrecy. The IRB and other representatives of this organization may inspect your information. Others include Truven Health Analytics and the Centers of Medicare and Medicaid Services.

If, during the course of this study, the assessor finds evidence of abuse, neglect, or reportable disease, this information may be required to be disclosed to the appropriate authorities.

What else do I need to know?

This research is being funded by the Center for Medicare and Medicaid Services as part of the project called “Testing Experience and Functional Tools.”

If you agree to take part in this research study, we will provide you with a gift card for your time and effort. You will be asked to acknowledge receipt of this gift card on a separate form.

The results of this research will be written up in a report to the Centers for Medicare and Medicaid Services who will make the report available for public review at the conclusion of the study. This report will only include group descriptions of results. Because we are not collecting any personally identifying information you will not identified in this report.

Informed Consent for Research Participation

Signature Block for Adult

By signing below, you agree that the above information has been explained to you and you have had the opportunity to ask questions. You understand that you may ask questions about any aspect of this research during the course of the study and in the future. Your signature documents your permission to take part in this research.

_____

Printed name of subject

_____ _____

Signature of subject Date

_____ _____

Signature of person obtaining consent Date

PRA Disclosure Statement *According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1037 (Expires: TBD). If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.*

THE GEORGE WASHINGTON UNIVERSITY

WASHINGTON, DC

Research Study Assent

Principal Investigator: Dr. Trudy Mallinson

Study Title: Standardization of Functional Status Items

We are doing a research study about the Home and Community Based Services program that you are a part of. You are regularly asked questions to see what services you need in this program. This study will see if asking new questions helps better determine what services other people like you need. You don't have to take part in this study if you do not want to.

What will happen to me during this study?

If you choose to take part in this study, you will be asked questions about how much help you usually need to do everyday activities such as dressing, walking, and using the telephone. This should only take about an hour. You do not have to answer any questions if you don't want to, and you can stop participating at any time.

What are the study risks? Can anything bad happen to me by doing this study?

You might feel a little uncomfortable with the questions that are asked.

Taking part is up to you. If you decide to take part and then change your mind you can quit at any time. If you choose not to be in the study, nothing will happen. Your decision to take part or not will not affect the services or benefits provided to you by your state.

What are the study benefits? Can anything good happen to me by doing this study?

There are no direct benefits to you by being in the study. The benefits are to make the program better and better help people like you who are in the program.

Will anyone know I am in the study?

If you decide to take part in the study, your personal information and your answers will be kept secret. Your name will not be on the study forms. Your answers will be shared with the study sponsor (The Centers for Medicare and Medicaid Services) and with the researchers who are conducting the study. They are not allowed to share your answers with anyone else.

Who can I talk to about the study?

If you have any questions about this study, or any problems with the study, you or your guardian can call Trudy Mallinson, the study director, at (202) 994-6833.

If you have questions about the study but want to talk to someone who is not part of the study, you can call The Office of Human Research of George Washington University, at telephone number (202) 994-2715.

What if I do not want to do this?

You do not have to be in the study. You can stop being in the study at any time without getting into trouble with your care providers and it will not affect the program services you receive. Even if you say yes now, you can change your mind later. If you don't want to be in the study later, please tell the study director, Trudy Mallinson, (202) 994-6833, at any time.

Signatures

Before deciding if you want to be in the study, ask any questions you have. You can also ask questions during the time you are in the study.

If you sign your name below, it means that you agree to take part in this research study.

_____ _____

Your Name (Printed)

_____ _____

Your Signature Date

_____ _____

Signature of Person Obtaining Consent Date

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